

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI**

JESSICA ANTONACCI,

Plaintiff,

v.

ALLERGAN USA, INC.; ALLERGAN,
INC., n/k/a ABBVIE INC.; ALLERGAN
plc, n/k/a ABBVIE INC.; and ABBVIE
INC.,

Defendants.

Case No. 4:20-cv-01841-AGF

HON. AUDREY G. FLEISSIG

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS ALLERGAN USA, INC.
AND ALLERGAN, INC.'S MOTION TO DISMISS**

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I. INTRODUCTION

Plaintiff Jessica Antonacci’s Petition alleges various state law product liability and tort claims, all arising from her use of breast implants manufactured by the Allergan defendants (hereinafter “Allergan”).¹ Her implants are, however, Class III medical devices approved under the Federal Food and Drug Administration’s (“FDA”) rigorous Pre-Market Approval (“PMA”) process—the highest scrutiny FDA applies. Consequently, her claims challenging the design, manufacture, and labeling of her implants run squarely into well-settled federal preemption principles that compel dismissal of her claims with prejudice.

Before selling its Class III breast implants, Allergan had to demonstrate, to the satisfaction of FDA’s scientific experts, that they were safe and effective for their intended use. FDA’s safety and efficacy review employs the highest standards in the world and requires submission of thousands of pages of data, testing, and related information concerning a device’s design, manufacture, and labeling. After its expert review, FDA established device-specific requirements that Allergan was required to follow. Those requirements could not be altered by Allergan without further FDA evaluation and approval.

To protect the efficacy and vitality of FDA’s regulation and oversight over Class III medical devices, Congress enacted an express preemption provision that forecloses state interference with the regulatory process: “[N]o State may establish or continue in effect” any laws or regulations that are “different from, or in addition to, any requirement” made applicable to the medical devices by FDA. 21 U.S.C. § 360k(a). To that same end, Congress also prohibits private enforcement of the implementing statutes and regulations, and instead requires the United States

¹ Specially appearing Defendants Allergan plc (n/k/a Allergan Limited) and AbbVie Inc. have moved separately to dismiss, for lack of jurisdiction and for insufficient service on Allergan plc.

to bring all “proceedings for the enforcement, or to restrain violations” of the applicable regulatory scheme. 21 U.S.C. § 337(a).

The legal import of these over-arching statutory provisions is well-documented in case law, including cases dealing with Class III breast implants. The twin pillars of the controlling express and implied preemption principles that follow from these two provisions are the United States Supreme Court’s decisions in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) and *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001). For its part, *Riegel* establishes that any state law tort claims that would hold a manufacturer liable for selling a product that complies with FDA’s device-specific requirements regarding design, manufacture or labeling are expressly preempted under 21 U.S.C. section 360k(a). *Buckman* makes clear that if the elements of the alleged state law tort claims are critically dependent on the standards set forth in federal statutes or regulations, then those claims are impliedly preempted to give effect to 21 U.S.C. section 337(a).

In application, *Riegel* and *Buckman* leave only a “narrow gap” for state law tort claims aimed at Class III medical devices like Plaintiff’s breast implants. That narrow gap exists only for those state law tort claims that truly parallel the device-specific requirements imposed by FDA’s approval. If the defendant’s conduct allegedly violates state law but not the federal requirements, it is not parallel because state law then effectively imposes requirements that are different from or in addition to the device-specific federal requirements.

Missouri courts—both state and federal—routinely dismiss personal injury/product liability lawsuits involving Class III medical devices as preempted. *See, e.g., Williams v. Bayer Corp.*, 541 S.W.3d 594, 599-605 (Mo. App. 2017); *Arthur v. Medtronic, Inc.*, 2014 U.S. Dist. LEXIS 110229 (E.D. Mo. Aug. 11, 2014); *see also In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1203-08 (8th Cir. 2010) (affirming dismissal of claims as

preempted under *Riegel* and *Buckman*). Indeed, the Tenth Circuit, in a case applying Missouri law, very recently affirmed a dismissal on preemption grounds of a case involving PMA-approved breast implants, just like the case at bar. *Brooks v. Mentor Worldwide LLC*, 2021 U.S. App. LEXIS 2085, at *7-*12 (10th Cir. Jan. 26, 2021) (applying Missouri law and affirming dismissal on preemption grounds in a case involving PMA-approved breast implants). This Court should do likewise and dismiss the Petition with prejudice.

II. BACKGROUND

The factual allegations relevant to this Motion to Dismiss are straightforward:

- (1) The Class III medical device at issue is a silicone-filled breast implant (Natrelle style Allergan SRX 560), implanted on September 2, 2008. (*See* Pet. (ECF 1-1) at ¶ 2.)
- (2) FDA approved the device through the PMA process.²

Although nothing more is required to sustain this Motion to Dismiss based on federal preemption, below is a more detailed background.

A. Class III Medical Devices Are Subject To Rigorous Evaluation And Oversight By FDA Before And After Approval

In 1976, Congress enacted the Medical Device Act (“MDA”), 21 U.S.C. sections 360c *et seq.*, to the FDCA, 21 U.S.C. sections 301 *et seq.* With the passage of the MDA, Congress established a detailed federal regime for regulating medical devices, such as those at issue here.

² *See* Pet., ¶¶ 15-16 (PMA required for breast implants); *see also Ulrich v. Pope Cty.*, 715 F.3d 1054, 1058 (8th Cir. 2013) (well pleaded facts in complaint accepted as true for purposes of a Rule 12(b)(6) motion.. Additionally, a record of FDA’s Premarket Approval is publicly available through the FDA’s website. *See*: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020056> (last accessed January 28, 2021) (FDA’s original PMA approval listing); <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020056S026> (last accessed January 28, 2021) (supplemental approval). This Court may take judicial notice of the PMA approval because the approval can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned. *See* Fed. R. Evid. 201(b)(2); *see also Arthur*, 2014 U.S. Dist. LEXIS 110229, at * 2 n.1 (taking judicial notice of FDA PMA approval); *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 938 n.1 (E.D. Mo. 2014) (same).

21 U.S.C. § 360c *et seq.* Under the MDA, different types of medical devices receive different levels of regulatory scrutiny. Class III medical devices “support[] or sustain[] human life” or “present[] a potential unreasonable risk of illness or injury.” 21 U.S.C. § 360c(a)(1)(C)(ii). Therefore, Class III devices invoke FDA’s strictest regulation through its PMA-approval process.

This Class III approval process is exhaustive and weighs the “probable benefit to health from the use of the device against any probable risk of injury or illness from such use.” 21 U.S.C. § 360c(a)(2)(C). FDA “spends an average of 1,200 hours reviewing each application,” *Riegel*, 552 U.S. at 317, and if FDA is not satisfied with the information provided, it can demand more, 21 U.S.C. § 360e(c)(1)(G). Moreover, in this process, FDA can require revisions to the device’s design, manufacturing methods, or labeling. *Riegel*, 552 U.S. at 319 (citing 21 C.F.R. § 814.44(e)). Once the process is completed, FDA’s approval imposes specific requirements extending to the device’s design and manufacturing, and conditions for use as provided in its labeling. *See* 21 C.F.R. § 814.20(b) (specifying PMA application requirements; 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A)). And, these device-specific requirements, whether related to the design, manufacture or labeling, must be adhered to and cannot be changed absent FDA approval. 21 C.F.R. §§ 814.39(a), 814.39(d) and 814.80.

FDA regulatory oversight continues after approval: “Once a device has received premarket approval, [federal law] forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness.” *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). Further, FDA may withdraw approval, and must do so if it determines that a device is unsafe or ineffective as labeled. *Id.* at 319-20 (citing 21 U.S.C. §§ 360e(e)(1), 360h(e)). A manufacturer must submit a PMA supplement to make any changes to a device’s design or instructions. 21 C.F.R. § 814.39.

Congress enforced exclusive FDA authority over Class III devices by enacting 21 U.S.C. § 360k(a), which provides that no state “may establish or continue in effect with respect to a device ... any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.” While preemption may leave some injured persons without recourse, the Supreme Court found this is a consequence of any preemption clause, and that this result is justified because many more “would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.” *Riegel* at 326. The breast implants at issue here are Class III devices and its approval has never been revoked, withdrawn, or suspended.

B. Plaintiff’s State Law Tort Claims Challenge FDA’s Device-Specific Requirements Applicable To Her Class III Implants

Plaintiff alleges she received her breast implants on September 2, 2008. (Pet., ¶2). She further alleges that she noticed a deformed appearance with her left breast and had the implants removed on January 29, 2019. (*Id.* at ¶¶ 4, 5.) She also alleges that during the removal surgery her doctor observed that the left implant had ruptured and was leaking. (*Id.* at ¶ 6.) Plaintiff claims that Defendants (1) failed to provide adequate warnings of—or otherwise concealed—the alleged risk of the implants rupturing (*id.* at ¶¶ 19-27, 33 & 56) and (2) failed to provide timely and adequate reports regarding potential safety hazards associated with the device (*id.* at ¶¶ 33 & 38-39). Plaintiff asserts state law tort claims against Allergan for negligence, strict liability, breach of implied warranty, and an alleged violation of the Missouri Merchandising Practices Act (the “MMPA”). (*See generally* Pet.) Plaintiff’s Petition pleads no specific facts in support of these allegations.

III. LEGAL STANDARD

A motion to dismiss should be granted when a complaint is insufficient to state a claim upon which relief can be granted. *See* Fed. R. Civ. P. 12(b)(6). A complaint must plead enough facts to state a claim for relief that is “plausible” on its face. *Bell Atlantic v. Twombly*, 550 U.S. 544, 555 (2007). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant[s] [are] liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). “[T]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.* Further, preemption is an issue of law for the court, and preempted claims are subject to dismissal under these standards. *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1680 (2019) (preemption is an issue of law); *Bass v. Stryker Corp.*, 669 F.3d 501, 508 (5th Cir. 2012) (affirming dismissal based on express preemption of state law tort claims for design and warning defects).

IV. LEGAL ARGUMENT

A. Plaintiff’s Claims Challenging The Safety And Effectiveness Of Her Class III Devices Are Expressly Preempted

The express preemption clause applicable to Class III medical devices provides “no State . . . may establish or continue in effect with respect to a device intended for human use any requirement”: (1) “which is different from, or in addition to, any requirement applicable under [the MDA] to the device”; and (2) “which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.” 21 U.S.C. § 360k.

As the Supreme Court observed in *Riegel*, express preemption is a two-step analysis. First, a court must determine whether “the Federal Government has established requirements applicable to” the particular medical device. *Riegel*, 552 U.S. at 321. If so, the court then must determine

whether the state law claims at issue are based upon requirements with respect to the device that are “different from, or in addition to” the federal requirements relating to the device’s: (i) “safety and effectiveness,” 552 U.S. at 316 (quoting 21 U.S.C. § 360k(a)); or (ii) “any other matter included in a requirement applicable to the device under [the MDA],” § 360k(a). If they do, the claims are expressly preempted.

Here, the first step in the analysis is satisfied as a matter of fact and law. As *Riegel* holds, for Class III devices like Plaintiff’s implants, “[p]remarket approval . . . imposes [federal] ‘requirements’” as that term is used in the preemption clause. 552 U.S. at 322. *Riegel* also holds, for the purposes of preemption under the MDA’s preemption clause, that state common law duties constitute “requirements” (552 U.S. at 324–25) and specifically, that “the duties underlying negligence, strict-liability, and implied-warranty claims” are requirements “with respect to devices.” *Id.* at 327 (internal quotation marks omitted).

As for the second step, in keeping with *Riegel*’s reasoning and holding, state common law causes of action that impose “different” or “addition[al]” duties relating to any requirement imposed by FDA on a Class III device are expressly preempted by 21 U.S.C. section 360k(a). Missouri appellate courts, as well as other courts across the country, apply this “different from or in addition to” principle in finding state law tort claims involving Class III medical devices preempted, just as *Riegel* commands. See *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 988-89 (E.D. Mo. 2014) (failure to warn expressly preempted); *Zaccarello v. Medtronic, Inc.*, 38 F. Supp. 3d 1061, 1066-69 (W.D. Mo. 2014) (negligence, strict liability, and failure to warn claims all preempted); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 (7th Cir. 1997) (plaintiff’s “negligence claims must be considered preempted to the extent that they allege that [defendant] was negligent despite its adherence to the standards required by the FDA in its PMA”). Indeed,

since *Riegel*, numerous courts have found product liability claims involving breast implants preempted in their entirety. *See, e.g., Brooks*, 2021 U.S. App. LEXIS 2085, at *7-*12 (10th Cir. Jan. 26, 2021).³

Here, Plaintiff's claims are all based on Missouri law and challenge the safety of Plaintiff's Class III medical devices. (*See, e.g., Pet.* at ¶¶ 44-49.) Because Plaintiff would require Allergan to have used a different design or warning than those approved by FDA, Plaintiff's claims would impose different or additional state law requirements and are expressly preempted and should be dismissed. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1206 (claims preempted "absent concrete allegations that the product sold by [the defendant] was not the product design approved" by the FDA") (internal quotations omitted); *Zaccarello*, 38 F. Supp. 3d at 1066-69; *Arthur*, 2014 U.S. Dist. LEXIS 110229, at *18-19; *Blankenship*, 6 F. Supp. 3d at 988-89; *see*

³ Additional decisions include: *Ebrahimi v. Mentor Worldwide LLC*, 804 F. App'x 871 (9th Cir. 2020), *affirming* 2017 WL 4128976 (C.D. Cal. Sept. 15, 2017), 2018 WL 2448095 (C.D. Cal. May 25, 2018), and 2018 WL 6829122 (C.D. Cal. Dec. 27, 2018); *D'Addario v. Johnson & Johnson*, 2020 WL 3546750 at *4-*5 (D.N.J. June 30, 2020); *Diodato v. Mentor Worldwide LLC*, 2020 WL 3402296, at *2-*3 (D. Md. June 19, 2020); *Webb v. Mentor Worldwide LLC*, ___ F. Supp. 3d ___, 2020 WL 1685323, at *4-*7 (N.D.N.Y. April 7, 2020); *Jacob v. Mentor Worldwide, LLC*, 393 F. Supp. 3d 912, 923-26 (C.D. Cal. 2019); *Vieira v. Mentor Worldwide, LLC*, 392 F. Supp. 3d 1117, 1128-32 (C.D. Cal. 2019); *Jacob v. Mentor Worldwide, LLC*, 389 F. Supp. 3d 1024, 1028-30 (M.D. Fla. 2019), *amended complaint dismissed*, 2019 WL 6766574, at *3 (M.D. Fla. Dec. 10, 2019); *Tinkler v. Mentor Worldwide, LLC*, 2019 WL 7291239, at *4-*5 (S.D. Fla. Dec. 30, 2019); *Williams v. Mentor Worldwide LLC*, 2019 WL 4750843, at *4-*6 (N.D. Ohio Sept. 30, 2019); *Brooks v. Mentor Worldwide, LLC*, 2019 WL 4628264, at *4-*7 (D. Kan. Sept. 23, 2019), *aff'd* 2021 U.S. App. LEXIS 2085, at *7-*12 (10th Cir. Jan. 26, 2021); *Sewell v. Mentor Worldwide, LLC*, 2019 WL 4038219, at *7-*10 (C.D. Cal. Aug. 27, 2019); *Billetts v. Mentor Worldwide, LLC*, 2019 WL 4038218, at *7-*9 (C.D. Cal. Aug. 27, 2019); *Stampley v. Allergan USA, Inc.*, 2019 WL 1604201, at *3 (W.D. La. March 15, 2019), *adopted*, 2019 WL 1601613 (W.D. La. April 15, 2019); *Shelp v. Allergan, Inc.*, 2018 WL 6694287, at *2 (W.D. Wash. Dec. 20, 2018); *Laux v. Mentor Worldwide, LLC*, 2017 WL 5186329, at *2-*4 (C.D. Cal. Nov. 8, 2017), *aff'd*, 786 F. App'x 84 (9th Cir. 2019); *Ortiz v. Allergan, Inc.*, 2015 WL 5178402, at *4-*5 (S.D.N.Y. Sept. 4, 2015); *Lindler v. Mentor Worldwide LLC*, 2014 WL 6390307, at *2 (D.S.C. Oct. 23, 2014); *Malonzo v. Mentor Worldwide, LLC*, 2014 WL 2212235, at *2-*3 (N.D. Cal. May 28, 2014); *Couvillier v. Allergan, Inc.*, 2011 WL 8879258, at *1 (W.D. La. Jan. 20, 2011), *adopted*, 2011 WL 8879259 (W.D. La. Feb. 9, 2011); *Williams v. Allergan USA, Inc.*, 2009 WL 3294873, at *2-*5 (D. Ariz. Oct. 14, 2009) (investigational implant); *Dorsey v. Allergan, Inc.*, 2009 WL 703290, at *5-*7 (M.D. Tenn. March 11, 2009) (investigational implant); *Cashen v. Johnson & Johnson*, 2018 WL 6809093, at *7-*11 (New Jersey Super. L.D. Dec. 24, 2018).

also *Chambers v. Osteonics Corp.*, 109 F.3d 1248 (7th Cir. 1993) (state-law claims “‘set up a direct collision with federal policy’ because the FDA has already decided, rightly or wrongly, that a particular device can be sold”).

B. Plaintiff’s Claims Are Also Impliedly Preempted

Even if a claim survives express preemption under *Riegel* (and here none do), courts also must determine whether it is barred by 21 U.S.C. § 337(a) or impliedly preempted, including under *Buckman*, before allowing it to proceed. In enacting the FDCA, Congress declined to create a private right of action and instead required that any action to enforce the FDCA “shall be by and in the name of the United States.” 21 U.S.C. § 337(a). The FDCA mandates that the Act and its implementing regulations be “enforced exclusively by the Federal Government” (*Buckman*, 531 U.S. at 352), and that state law causes of action for violations of the FDCA are barred under the doctrine of implied preemption. *See Blankenship*, 6 F. Supp. 3d at 986. Section 337(a) therefore impliedly preempts any private action to enforce duties created by the federal regulations. *In re Medtronic Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1204. Pursuant to *Buckman* and §337(a), Plaintiff’s claims against Allergan should be dismissed with prejudice because they effectively seek to enforce purported federal regulations. Such claims are impliedly preempted. *See Blankenship*, 6 F. Supp. 3d at 989-91 (failure to report adverse events to FDA and negligence claims impliedly preempted).

C. Plaintiff Fails To Plead Any Viable Parallel Claim

To withstand preemption, a plaintiff must allege a “parallel claim” that involves a state-law duty that is parallel to, instead of adding to or differing from, the duty imposed by federal requirements specific to the device. *See Riegel*, 552 U.S. at 330. This leaves only a “narrow gap” through which a plaintiff’s state-law claim must fit: The plaintiff must be suing for “‘conduct that *violates* the FDCA . . . but not be suing *because* the conduct violates the FDCA.’” *In re Medtronic*,

Inc., Sprint Fidelis Leads Prod. Liab. Lit., 623 F.3d at 1204 (emphasis added). To be parallel, the state and federal requirements must be “genuinely equivalent” if not “identical.” *Otis-Wisher v. Medtronic, Inc.*, 616 F. App’x 433, 434 (2d Cir. 2015) (identical); *Blankenship*, 6 F. Supp. 3d at 986 (genuinely equivalent (citing *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005))); *see also Wolicki-Gables v. Arrow Int’l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011).

Further, to get through that narrow gap, a plaintiff “must set forth facts pointing to *specific* [premarket approval] requirements that have been violated and link those violations to his injuries.” *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 403 (S.D.N.Y. 2013) (citing *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 249-50 (S.D.N.Y. 2013)) (internal citations omitted) (emphasis added). “To the extent that a plaintiff fails to plead a manufacturer’s noncompliance with a particular condition of premarket approval, a parallel claim will fail.” *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 494-95 (W.D. Pa. 2012) (internal citation omitted). A “plaintiff cannot simply incant the magic words ‘Defendant violated FDA regulations’ in order to avoid preemption.” *Zaccarello*, 38 F. Supp. 3d at 1069 (citations and quotations omitted); *see also Burgos v. Satiety, Inc.*, 2010 WL 4907764, at *4 (E.D.N.Y. Nov. 30, 2010) (“opaque reference” to “statutes, codes, laws, ordinances, rules [or] regulations” insufficient to state a valid parallel claim).

Here, Plaintiff has failed to plead any proper parallel claim in the Petition, and thus her claims cannot survive a motion to dismiss based on implied preemption.

1. General Allegations of Negligence, Strict Liability and/or Breach of Implied Warranty Do Not State Parallel Claims

As a threshold matter, Plaintiff’s allegations that Allergan was negligent generally and/or should be held strictly liable – that it should not have sold an allegedly dangerous product – are not “parallel”; rather, they fall squarely into the range of claims that federal law preempts. To

survive preemption, a claim must allege facts that plausibly indicate that violations of federal regulations resulted in a plaintiff's injuries. *See, e.g., Blankenship*, 6 F. Supp. 3d at 986 ("to properly allege parallel claims, the complaint must set forth facts pointing to specific [federal] requirements that have been violated") (quoting *Wolicki-Gables*, 634 F.3d at 1301). Without an FDA regulatory hook – and adequate fact pleading about how the particular device deviated from federal requirements – such vague allegations fail as a matter of law. *Blankenship*, 6 F. Supp. 3d at 986; *Zaccarello*, 38 F. Supp. 3d at 1069; *see also Burkett v. Smith & Nephew GmbH*, 2014 WL 1315315, at *4 (E.D.N.Y. Mar. 31, 2014) (dismissing design defect claim because plaintiff did not allege that defendant "altered the design of the device from the design approved by the FDA"); *Cordova v. Smith & Nephew, Inc.*, 2014 WL 3749421, at *6 (E.D.N.Y. July 30, 2014) ("Because [plaintiff] does not claim that the design of the [device] differed from the design approved by the FDA, [plaintiff's] design defect claim boils down to a direct attack on the very design approved by the FDA.").

Similarly, Plaintiff's breach of implied warranty claim – *i.e.*, the allegation that the implants were unsafe for ordinary use – is "expressly preempted on its face." *Williams*, 541 S.W.3d at 604-05 (argument that device "by its very nature unfit for the ordinary purpose for which it is sold" would contradict FDA approval). Plaintiff, by asserting that Allergan should not have sold the device because of alleged defects, is essentially arguing that FDA never should have granted PMA for the device in the first place. Preemption affords no opportunity for this type of challenge. *Mitchell*, 126 F.3d at 915 (any claim based on "standards other than those permitted by the FDA would necessarily interfere with the PMA process and, indeed, supplant it," and are thus preempted); *see also Arthur*, 2014 U.S. Dist. LEXIS 110229, at *21-22 (Missouri breach of

implied warranty claims preempted because “[f]ederal law governs all statements that [device manufacturer] is obligated to make concerning the” device).

2. Plaintiff’s Allegations of Failure to Warn and Failure to Report Adverse Events Similarly Do Not State Parallel Claims

The Eighth Circuit’s binding decision in the *Sprint Fidelis Leads* case dictates that Plaintiff’s allegations that Allergan failed to warn Plaintiff and her physician, and failed to report adverse events to FDA, do not escape preemption. The Court of Appeals explained that FDA’s approval in the PMA process includes “specific language for Class III device labels and warnings.” *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1205. Accordingly, any claims premised on the allegation that a manufacturer should have provided warnings in addition to those set by FDA necessarily seek to impose requirements that are “different from or in addition to” the federal requirements, and are therefore expressly preempted. *Id.*; *see also Brooks*, 2021 U.S. App. LEXIS 2085, at *10-*11 (10th Cir. Jan. 26, 2021) (Missouri claims based on duty to warn plaintiff and/or plaintiff’s physician preempted). And so too, here, Plaintiff’s strict liability and MPPA failure-to-warn claims, which would purport to impose warning requirements above and beyond what FDA required, are expressly preempted under 21 U.S.C. § 360k(a) and must be dismissed with prejudice. *See Arthur*, 2014 U.S. Dist. LEXIS 110229, at *18 (dismissing failure-to-warn claim because “For plaintiff to prevail, a jury would have to find that defendants were required to include warning beyond those in the FDA-approved label for the” device) (citations omitted).⁴

⁴ Plaintiff’s failure-to-warn claims fail for the additional reason that, under the “learned intermediary doctrine,” any duty to warn is discharged when the warning is given to the physician. *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404, 419 (Mo. Ct. App. 1999). Under Missouri law, however, a manufacturer selling a product to a particular industry—such as a medical device manufacturer selling medical devices to doctors—is not required to warn against risks where the industry is already “well aware” of those risks. *DG&G, Inc. v. FlexSol Packaging Corp.*, 576 F.3d 820, 824 (8th Cir. 2009) (applying Missouri law); *see also Grady v. Am. Optical Corp.*, 702 S.W.2d 911, 915 (Mo. Ct. App. 1985) (“If the user of a product knows or reasonably may be expected to

Nor may Plaintiff evade preemption by grounding her claim in an allegation that Allergan failed to report to FDA the alleged defects/risks association with use of the device.⁵ Such a claim, the Eighth Circuit held, is impliedly preempted under *Buckman*. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1206 (allegation that manufacturer “failed to provide the FDA with sufficient information and did not timely file adverse event reports as required by federal regulations” are “foreclosed” by *Buckman*). The Tenth Circuit, applying Missouri law, reached the same conclusion. *Brooks*, 2021 U.S. App. LEXIS 2085, at *11-*12 (10th Cir. Jan. 26, 2021) (claims regarding post-PMA-approval testing and adverse event reporting preempted under *Buckman* because “only the federal government may enforce reporting requirements...”); *see also Lofton v. McNeil Cons. & Spec. Pharm.*, 672 F.3d 372, 376 (5th Cir. 2012) (recognizing that state law imposing “tort liability for failure to comply with FDA disclosure requirements” is impliedly preempted under *Buckman*); *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017) (adverse reporting theory impliedly preempted); *Marsh v. Genentech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012) (same).

In any event, Plaintiff’s allegations about adverse reporting are inadequate. She does not identify a single instance in which Allergan failed to submit an adverse-event report when required to do so. To avoid dismissal, the complaint must contain “some factual basis from which it can plausibly inferred that such [an] event occurred and that Defendants failed to report [it].” *Shuker v. Smith & Nephew PLC*, 2015 WL 1475368, at *16 (E.D. Pa. Mar. 31, 2015). Here, however,

know of a particular danger, strict liability will not result from a failure to warn of that danger”). Here, Plaintiff in her Petition states that the risks associated with the implants were widely known. (Pet. ¶20 (“the Natrelle style breast implants’ health risks were known in the scientific and medical community at the time of their manufacture, distribution, or sale).) Accordingly, her failure-to-warn claims fail under state *and* federal law.

⁵ Adverse-event reports are anecdotal rather than “valid scientific evidence” and they do not suggest that FDA believes the device caused or contributed to the reported event. *See* 21 C.F.R. § 814.20(b)(3)(vi).

“Plaintiff[] ... ha[s] not alleged any factual support for [her] claims, such as any details ... about any adverse events that should have been reported.” *Martin v. Medtronic, Inc.*, 63 F. Supp. 3d 1050, 1058 (D. Ariz. 2014). Plaintiff also does not allege *any* facts sufficient to establish a causal nexus between an alleged failure to investigate and report adverse events and her alleged injuries, and dismissal is warranted for this reason as well. *See, e.g., Martin*, 63 F. Supp. 3d at 1058 (dismissing failure-to-warn claim based on alleged failure to submit adverse-event reports to FDA where “Plaintiffs ... have not alleged how defendants’ alleged failure to warn the FDA about adverse events contributed to their injuries”).⁶

Put simply, Plaintiff’s failure-to-warn claims are preempted and should be dismissed.

V. CONCLUSION

On analysis, Plaintiff’s Petition amounts to nothing more than a set of state law tort claims that many cases have held do not fit through the narrow gap of federal preemption. Plaintiff’s claims, whether in strict liability or negligence, all would require something different from or in addition to the device-specific requirements applicable to her implants. In these circumstances, case law compels that federal preemption principles be given the effect Congress intended. There is no place for state tort law to insert itself on a record like this one, and this Court should grant Allergan’s motion and so hold.

Dated: January 29, 2021

⁶ Plaintiff also makes a passing allegation in her Petition that the device at issue was recalled by the FDA (Pet. at ¶ 3), but she does not (and cannot) assert that the recall had anything to do with defects she complains of here. Nor has she linked the recall to any of her claims. (*See generally*, Pet.) But more broadly, recalls simply have no bearing on the preemption analysis. Device recall, which is governed by 21 U.S.C. § 360h(e), does not invalidate a device’s PMA, the withdrawal of which is governed separately by § 360e(e). A PMA remains valid unless and until FDA expressly withdraws it pursuant to specified procedures. *See* 21 C.F.R. § 814.46; *see also Simmons v. Boston Sci. Corp.*, 2013 WL 1207421, at *4 (C.D. Cal. Mar. 25, 2013) (preemption motion granted although device was subject of corrective action classified by FDA as a recall); *Franklin v. Medtronic, Inc.*, 2010 WL 2543579, at *10 (D. Colo. May 12, 2010) (same).

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 29th day of January, 2021, a true and accurate copy of the foregoing was filed electronically using the Court's CM/ECF system, to be served via operation of the Court's electronic filing system upon all counsel of record.

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